

REMARKS

The Claim Amendments

Applicants have amended claim 19 to remove the dependency on claims 1, 2, 3, 4 and 5 and to recite specific polynucleotides of claim 1. Support for this amendment is found in the claims as filed. Applicants also have amended claim 19 to recite “cancer” instead of “CYP3A5 associated disease.” Support for this amendment is found throughout the application, for example, at page 13, lines 8-10.

None of the amendments goes beyond the application as filed. Their entry is requested. Upon entry of the amendments, claims 1-44 will be pending, of which claims 1-18 and 20-44 are withdrawn.

The Election/Restriction Requirement

The Examiner has proposed restriction of the claims of this application under 35 U.S.C. 121 to one of the following ten groups:

- I. Claims 1-8, 17, 18, 36, 37, 44, drawn to a polynucleotide;
- II. Claim 9, drawn to a method of making a molecular variant of a CYP3A5 polypeptide using host cells;
- III. Claim 10, drawn to making host cells expressing a molecular variant of a CYP3A5 polypeptide;
- IV. Claims 11, 17, 18, 36, 37, 44, drawn to a polypeptide;
- V. Claims 12-14, 17, 18, 36, 37, 44, drawn to an antibody;

- VI. Claims 15-16, 44, drawn to a transgenic animal;
- VII. Claim 19, drawn to a method of identifying a polymorphism;
- VIII. Claims 20-28, drawn to a method of identifying a pro-drug;
- IX. Claims 29-35, drawn to a method of diagnosing a disorder;
- X. Claims 38-43, drawn to a method of preparing a composition.

Applicants elect Group VII, drawn to a method of identifying a polymorphism. Group VII includes claim 19. Applicants make this election expressly without waiver of their right to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or by filing divisional or continuing applications claiming priority and benefit from this application.

The Examiner has further required election of one of the following polynucleotide sequences:

- 1) once specific polynucleotide sequence from subpart a, or
- 2) one specific nucleotide sequence from subpart b, or
- 3) one polynucleotide from subpart c including a specific position to be modified along with the modification to be made identified in subpart d of the claims, or
- 4) one specific nucleotide sequence from subpart e including a specific position to be modified along with the specific modification to be made, or
- 5) one specific nucleotide sequence from subpart f including the specific position to be modified along with the specific amino acid modification to be made.

Applicants traverse the restriction between the polynucleotides subparagraphs

- (a), (b), and (c) of claim 1 as filed.

According to the Manual of Patent Examining Procedure (MPEP) § 803, restriction of patentably distinct inventions is proper if two criteria are met: (1) the inventions must be independent or distinct as claimed, and (2) there must be a serious burden on the Examiner if restriction is required. MPEP § 803 further states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."

Claim 19, as amended, refers to isolating a polynucleotide selected from a polynucleotide having the nucleic acid sequence of SEQ ID NO: 112 (a); a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 141 (b); and a polynucleotide capable of hybridizing under stringent conditions to a CYP3A5 gene, wherein said polynucleotide has an additional nucleotide at a position corresponding to position 27131/27132 of the CYP3A5 gene as defined by the joined sequences of Accession No: AF280107.1, wherein position 166220 has been numbered +1 and position 174832 has been numbered +8613, and Accession No: AC005020.2, wherein position 27341 has been numbered +8614 (c).

A search for polynucleotide capable of hybridizing under stringent conditions to a CYP3A5 gene, wherein said polynucleotide has an additional nucleotide at a position corresponding to position 27131/27132 of the CYP3A5 gene would identify a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 141 and also would identify a polynucleotide of SEQ ID NO: 112.

Applicants request that these sequences be examined together because there is

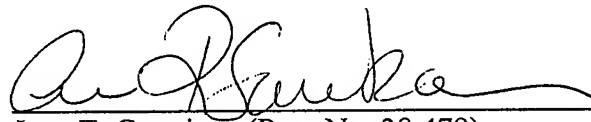
- no serious search burden for the Examiner to do so. If the Examiner does not agree with this proposal, pursuant to 37 C.F.R. § 1.143, applicants provisionally elect with traverse SEQ ID NO: 112 for examination.

Applicants make this species election expressly without waiver of their right to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or by filing divisional or continuing applications claiming priority and benefit from this application.

CONCLUSION

If the Examiner believes that a telephone conference with applicants' representatives would be helpful, the Examiner is invited to telephone the undersigned at anytime. Applicants request favorable consideration of the application and early allowance of the pending claim.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Jane T. Gunnison", written over a horizontal line.

Jane T. Gunnison (Reg. No. 38,479)
Attorney for Applicants
Anupama R. Sawkar (Reg. No. 59,399)
Agent for Applicants
Fish & Neave IP Group
ROPES & GRAY LLP
Customer No. 1473
1211 Avenue of the Americas
New York, New York 10036
Phone: 212.596.9000
Fax: 212.596.9090